

Docket # DURE-303

CLAIMS:**RECEIVED
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1. **(Currently Amended)** A stable nonaqueous drug formulation comprising:
at least one drug; and
a nonaqueous, single-phase vehicle comprising at least one polymer and at least one solvent, the vehicle being miscible in water,
wherein the drug is insoluble in one or more vehicle components and the drug formulation is stable at 37° C for at least two months; and
wherein the polymer was treated with methionine in an amount sufficient to reduce vehicle peroxide values below 5 ppm.
2. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein less than about 35% of the drug is degraded by chemical pathways.
3. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein less than about 15% of the drug is degraded through aggregation.
4. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein the drug comprises a particulate material.
5. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein the drug comprises medicines, vitamins, nutrients, or food supplements.
6. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein the drug comprises a peptide or protein.
7. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein the drug is selected from the group consisting of adrenocorticotropic hormone, angiotensin I and II, atrial natriuretic peptide, bombesin, bradykinin, calcitonin, cerebellin, dynorphin N, alpha and beta

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endorphin, endothelin, enkcephalin, epidermal growth factor, fertirelin, follicular gonadotropin releasing peptide, galanin, glucagon, GLP 1, gonadorelin, gonadotropin, goserelin, growth hormone releasing peptide, histrelin, human growth hormone, insulin, interferons, leuprolide, LHRH, motilin, nafarerlin, neuropeptides, oxytocin, relaxin, somatostatin, substance P, tumor necrosis factor, triptorelin, vasopressin, growth hormone, nerve growth factor, blood clotting factors, ribozymes, and antisense oligonucleotides.

8. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein the at least one polymer is selected from the group consisting of polyesters, pyrrolidones, esters of unsaturated alcohols, ethers of unsaturated alcohols, polyoxycylenepolyoxypropylene block copolymers, and combinations thereof.

9. **(Withdrawn)** The stable nonaqueous drug formulation of claim 1, wherein the at least one solvent is selected from the group consisting of glycofurool, tetraglycol, n methylpyrrolidone, glycrol formal, glycerine, propylene glycol, and combinations thereof.

10. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein the vehicle has a viscosity in the range of about 1,000 to about 250,000 poise when measured at 37° C at a shear rate of 10 4/sec using a parallel plate rheometer.

11. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein the vehicle comprises about 40% to about 80% (wt/wt) polymer and about 20% to about 60% (wt/wt) solvent.

12. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein the at least one drug comprises a dry, particulate material.

13. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein the vehicle exhibits a moisture content of less than 5%.

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14. **(Withdrawn)** The stable nonaqueous drug formulation of claim 1, wherein the vehicle comprises glucofurool as a solvent and polyvinylpyrrolidone as polymer.

15. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein the vehicle comprises benzyl alcohol as a solvent and polyvinylpyrrolidone as polymer.

16. **(Cancelled)**

17. **(Original)** The stable nonaqueous drug formulation of claim 1, wherein the at least one drug is dispersed within the vehicle as a suspension.

18. **(Withdrawn)** A drug delivery device comprising:

a reservoir having at least one drug delivery orifice;
a drug formulation contained within the reservoir, the drug formulation comprising a drug dispersed in a nonaqueous, single-phase vehicle;
the nonaqueous, single-phase vehicle comprising at least one polymer and at least one solvent, the vehicle being miscible in water;
wherein the drug is not soluble in one or more vehicle components and the drug formulation is stable at 37° C for at least two months.

19. **(Withdrawn)** The drug delivery device of claim 18, wherein the device is an implantable osmotic pump and the reservoir comprises an osmotic agent.

20. **(Withdrawn)** The drug delivery device of claim 18, wherein the device is configured to deliver the drug formulation at a rate of less than 100 microliters per day.

21. **(Withdrawn)** The drug delivery device of claim 18, wherein the device is configured to deliver the drug formulation during a period of time greater than one day.

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22. **(Withdrawn)** The drug delivery device of claim 18, wherein the drug comprises a particulate material.

23. **(Withdrawn)** The drug delivery device of claim 18, wherein the drug comprises medicines, vitamins, nutrients, or food supplements.

24. **(Withdrawn)** The drug delivery device of claim 18, wherein the drug comprises a peptide or protein.

25. **(Withdrawn)** A method for preparing a stable nonaqueous drug formulation comprising:

providing a nonaqueous, single-phase vehicle comprising at least one polymer and at least one solvent, the vehicle being miscible in water;

providing a dry, particulate drug material, wherein the drug material is insoluble in one or more vehicle components; and

mixing the drug material with the vehicle to form a drug formulation that is stable at 37° C for at least two months.

26. **(Withdrawn)** The method of claim 25, wherein providing a dry, particulate drug material comprises providing a drug material that has undergone spray drying, lyophilization, dessication, granulation, grinding, milling, precipitation, homogenization, or coating processes.

27. **(Withdrawn)** The method of claim 25, wherein mixing the drug material with the vehicle is performed without the addition of water.

28. **(Withdrawn)** The method of claim 25, wherein providing a dry, particulate drug material comprises providing medicines, vitamins, nutrients, or food supplements.

29. **(Withdrawn)** The method of claim 25, wherein providing a dry, particulate drug material comprises providing a peptide or protein.

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30. **(Withdrawn)** The method of claim 25, wherein the at least one polymer is selected from the group consisting of polyesters, pyrrolidones, esters of unsaturated alcohols, ethers of unsaturated alcohols, polyoxyethylenepolyoxypropylene block copolymers, and combinations thereof.

31. **(Withdrawn)** The method of claim 25, wherein the at least one solvent is selected from the group consisting of glycosurol, tetraglycol, n methylpyrrolidone, glycerol formal, glycerine, propylene glycol, and combinations thereof.